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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/490,291	01/20/2000	Charlene Mello	NA-1151	6968

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EXAMINER

SCHNIZER, HOLLY G

ART UNIT PAPER NUMBER

1653

DATE MAILED: 05/31/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

**FILE COPY****Office Action Summary**

Application No.

60/490,291

Applicant(s)

MELLO ET AL.

Examiner

Holly Schnizer

Art Unit

1653

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 06 March 2002.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-16 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 1-20-00 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)      4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

6) Other: \_\_\_\_\_

## DETAILED ACTION

### *Status of the Claims*

1. The Response and Amendment filed March 6, 2002 (Paper No. 14) has been entered. Claim 18 has been cancelled. Therefore, Claims 1-16 are pending and have been considered on the merits in this Office Action.

### *Rejections Withdrawn*

2. The rejection of Claims 7, 8, 12, and 13 under 35 U.S.C. 112, second paragraph, as being indefinite for omitting an essential step is withdrawn in light of the amendment to the claims.
3. The rejection of Claims 1-16 and 18 under 35 U.S.C. 112 second paragraph as being unclear as to what endpoint or goal the method achieves is withdrawn in light of the amendment to the claims.
4. The rejection of Claims 9-16 under 35 U.S.C. 112, second paragraph as unclear as to where the "insoluble material" of part c (in Claim 9 for example) comes from since the claims recite that "treating" in part b includes the step of "clarifying" is withdrawn in light of the amendment to the claim.
5. The rejection of Claims 7, 12, and 16 under 35 U.S.C. 112, first paragraph, scope of enablement is overcome by the amendment indicating that insoluble fibers of polypeptides are produced.

***Rejections Maintained***

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3-9, 11-14 and 16 are again rejected under 35 U.S.C. 102(b) as being anticipated by Lombari et al.

3. The previous rejections stated: The Lombari et al. reference teaches a method of purifying and producing concentrated amounts of recombinant and non-recombinant spider silk proteins by solubilization, a host bacterial cell containing the polypeptide and use of organic acids including propionic acids for recovery of concentrated protein. (See Col. 2, line 10-Col. 5, line 47).

4. Applicant's argument that the claims have been amended to describe the recovered solution as comprising one or more purified polypeptides implying that Lombari et al. do not teach purifying the protein has been considered but is not deemed persuasive for the following reasons. The method of Lombari et al. still has the exact same steps as the claimed invention (as described in the paragraph immediately above). Moreover, Lombari et al. teach that the proteins discussed therein should be recovered "in a substantially pure form that is suitable for commercial applications" (Col. 4, lines 38-39). Lombari et al. also states "a preferred form of a recombinant spider silk

protein is one that provides a single peak in a conventional high-performance liquid chromatography column" (Col. 5, lines 25-30).

Thus, the claims remain anticipated by Lombari et al.

***New Rejections Necessitated by Amendment***

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 1 recites the limitation "said one or more purified polypeptides" in 3-4. There is insufficient antecedent basis for this limitation in the claim. Because of this lack of antecedent basis, the claim is unclear as to the point at which the structural polypeptides become purified. Are they provided in purified form or does the step of contacting the structural polypeptides with the acid result in the one or more purified polypeptides? This confusion is compounded by the lack of preamble indicating a goal of the method (is the claimed method a method of solubilizing the protein or is it a method of purifying the protein?). Claims 2-8 are rejected since they depend from indefinite base Claim 1 but do not correct its deficiencies.

4. Claims 8 and 13 are rejected since they fail to further limit Claims 7 and 12 from which they depend, respectively. For example, Claim 8 recites "the method of Claim 7,

wherein the fibers of polypeptides are produced". However, the last limitation of Claim 7 is "wherein insoluble fibers of polypeptides are produced". Claim 13 is identical except for the different claim numbers. Correction is required.

5. Claims 9-16, are unclear as to the purpose of step c in Claims 9 and 14. The result of step b is "to yield a recovered solution, said recovered solution comprising one or more purified polypeptides". Step c involves "recovering said one or more recombinant polypeptides in the recovered solution". The Specification defines "recovered" as locally sequestered and captured" (see p. 12). Thus, the claim is unclear as to what is involved in recovering the recombinant polypeptides in step c since they appear to have already been "recovered" in the recovered solution of step b.

Dependent Claims 10-13 and 15-16 are rejected since they depend from indefinite base Claims 9 and 14 but do not correct the deficiencies.

### ***Conclusions***

No claims are allowable. However, the methods of Claims 2, 10, and 15 appear to be free of the prior art. A thorough search of the sequence databases does not reveal any teaching or suggestion of the claimed methods wherein the polypeptide used in the method is selected from the sequences claimed in Claims 2, 10, and 15.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (703) 305-3722. The examiner can normally be reached on Mon. & Thurs., 8am-5:30pm and Tues. & Wed. 9-2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*HS*  
Holly Schnizer  
May 29, 2002

*Christopher S. F. Low*  
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